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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,940	08/24/2001	J. Bryan Jones	GC525-C3	3800

5100 7590 03/15/2004

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/938,940	JONES ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 January 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *26 January 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See Continuation Sheet*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *14-17,20-23,34 and 35*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit: 1652

Continuation of 2. NOTE: Applicants proposed amendment adding new claims 37-39 would require additional consideration and/or search after-final rejection. Applicants attention is further drawn to applicants newly presented set of claims which appears to be missing claims 18 and 19. Applicants are reminded that even in the event that these claims have been previously cancelled they must be listed as such. Claims 14-17, 20-23, 34 and 35 are still at issue and are present for examination. .

Continuation of 5. does NOT place the application in condition for allowance because: The rejections of record remain in light of the nonentry of applicants amendment and applicants comments.

Claims 14-17, 20-23, 34 and 35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
The rejection is stated in the previous office action. Applicants continue to traverse this rejection on the basis that in addition to applicant previous arguments, one of skill in the art would be able to recognize the claimed invention and what has been invented.
Applicants argument continues to be found not persuasive, for the reasons previously stated, and applicants are reminded that while it is acknowledged that a particular structure to function/activity relationship is not necessary to satisfy the Written Description requirements, such a disclosure is but one way in which applicants may achieve adequate written description. Other means include identifying characteristics such as partial structure, physical and/or chemical properties, functional characteristics, method of making and combinations of all of the above.

Claims 14-17, 20-23, 34 and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a chemically modified mutant Bacillus lentus subtilisin wherein the chemical modification corresponds to the replacement of amino acid residues N62, L217 and S166, with a cysteine residue, wherein the cysteine residue is modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selected from the group consisting of: -SCH2(p-CH3-C6H4), -SCH2(p-OCH3-C6H4), -SCH2(p-CF3-C6H4) and -SCH2(2,4-diNO2-C6H3), does not reasonably provide enablement for any chemically modified mutant enzyme with one or more amino acid residues replaced by a cysteine residue, wherein at least some of the cysteine residues are modified by replacing the thiol hydrogen in the cysteine residue with a thiol side chain, wherein the thiol side chain is selecte from the group consisting of: -SCH2(p-CH3-C6H4), -SCH2(p-OCH3-C6H4), -SCH2(p-CF3-C6H4) and -SCH2(2,4-diNO2-C6H3). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.
The rejection is stated in the previous office action.
Applicants argument continues to be found not persuasive, for the reasons previously stated. Applicants argue that applicants have taught how to make all the claimed species without undue experimentation and how test for functionality.
This is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., having protease activity) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity fo routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respec to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification.
Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any of the claimed chemically modified mutant enzymes having any activity or function. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim 16 remains rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 4 of prior U.S. Patent No. 6,284,512 B1. This is a double patenting rejection.

Claims 14, 15, 17, 20-23, 34 and 35 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 9 and 10 of U.S. Patent No. 6,284,512 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8, 9 and 10 of U.S. Patent No. 6,284,512 B1 anticipate claims 14, 15, 17-23, 34 and 35, respectively. Applicants statement regarding the filing of a supplemental amendment comprising a terminal disclaimer to follow shortl is acknowledged..